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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,979	03/22/2001	Gary de Jong	24601-416	7635

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,979

Applicant(s)

DE JONG ET AL.

Examiner

Daniel M Sullivan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004 and 23 July 2004 and 15 Oct.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32, 34-47, 59, 61-64 and 141-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-47, 59, 61-64 and 147 is/are allowed.
- 6) ☒ Claim(s) 1-32 and 141-146 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/21/04, 3/22/04
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

This Office Action is a reply to the Papers filed 21 June 2004, 23 July 2004 and 15 October 2004 in response to the Non-Final Office Action mailed 19 December 2003. Claims 1-57, 59, 61-83 and 141-147 were considered in the 19 December Office Action. Claims 1, 2, 9-11, 32 and 64 have been amended and claims 33, 48-57 and 65-83 have been canceled. Claims 1-32, 34-47, 59, 61-64 and 141-147 are pending and under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

Rejection of claims 1-32, 34-47, 59, 61-64 and 141-147 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendment of the claims such that they no longer recite that the method is practiced *in vivo* and the arguments of record.

Rejection of claims 1-32 and 144-146 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Claim Rejections - 35 USC § 102

Rejection of claims 1, 3-10, 12-14 and 30-32 under 35 U.S.C. 102(b) as being anticipated by Hadlaczky *et al.* is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 103

Rejection of claims 1, 2-17, 26-28, 30-32, 61-64, 144 and 146 under 35 U.S.C. 103(a) as being unpatentable over Hadlaczky *et al.* in view of Unger *et al.* is withdrawn in view of the amendments to the claims and the arguments of record.

Claims 141-143 stand rejected under 35 USC §103 as being unpatentable over Hadlaczky *et al.* in view of Unger *et al.* for reasons of record.

In the remarks (beginning at page 41) applicant argues that claimed kits would not be obvious over the cited art because, “Hadlaczky *et al.* does not teach or suggest any kits, much less the components of the instant kit claims that include an artificial chromosome, a delivery agent and reagents for sonoporation or electroporation” and “Unger *et al.* also does not teach or suggest any kits. Therefore, the combination of the cited references cannot result in the instantly claimed kits.” Applicant further argues that the references do not suggest assembly of any components into kits and that there is no suggestion in Hadlaczky *et al.* or Unger *et al.*, singly or in combination, of the desirability of combining large nucleic acid molecules such as an artificial chromosome, a delivery agent and a sonoporation or electroporation agent into a kit for delivering artificial chromosomes into cells.

These arguments have been fully considered but are not deemed persuasive. As stated in the previous Office Action, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the teachings of Hadlaczky *et al.* with the teachings of Unger *et al.* to obtain enhanced gene expression. Motivation to combine these teachings is found in Hadlaczky *et al.*, who teaches that the artificial chromosomes described

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therein are useful for expressing exogenous DNAs in a cell (see especially the fourth paragraph in column 17) and from Unger *et al.* who teaches that ultrasound enhanced gene expression in all of the cell lines tested (see especially Figure 4 and Table 1 and the captions thereto). Given the general desirability of obtaining enhanced gene expression from methods designed for expressing exogenous DNA, the skilled artisan clearly would be motivated to combine the teachings of Hadlaczky *et al.* and Unger *et al.* according to the instant claims. Thus, the skilled artisan would be motivated to combine an artificial chromosome with a delivery agent and a sonoporation or electroporation agent for the purpose of delivering the artificial chromosome into a cell. Although the particular order of the process steps recited in the present claims would not be obvious over the art, it would be obvious to combine the components used in the method for the reasons set forth in the previous Office Action. The instant specification provides no definition of a "kit" that would distinguish a "kit" from a teaching that the components of the kit should be used together and, therefore, logically be present in the same place at the same time.

Applicant's arguments have been fully considered but, in view of the record as a whole, are not found persuasive. Therefore, the claims properly stand rejected under 35 USC §103.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 and 144-146 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting in part (b) "or applying a delivery agent". It is unclear to what the delivery agent is being applied in that step.

Claims 2-32 and 144-146 are indefinite insofar as they depend from claim 1.

Allowable Subject Matter

Claims 34-47, 59, 61-64 and 147 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

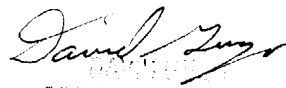
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636


PATENT EXAMINER